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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/791,895	03/04/2004	Christian Keller	7346	5189

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SHLESINGER, ARKWRIGHT & GARVEY LLP
1420 KING STREET
SUITE 600
ALEXANDRIA, VA 22314

EXAMINER	
JACKSON, BRANDON LEE	
ART UNIT	**PAPER NUMBER**
3772	

MAIL DATE	DELIVERY MODE
11/12/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/791,895	KELLER ET AL.	
	Examiner	Art Unit	
	BRANDON JACKSON	3772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 August 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,10-13 and 22-24* is/are pending in the application.

4a) Of the above claim(s) *3,5,6 and 13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4,10-12 and 22-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/18/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This office action is in response to amendments/arguments filed 8/15/2008. Currently, claims 1-6, 10-13, and 22-24 are pending in the instant application.

Response to Arguments

Applicant's arguments filed 8/15/2008 have been fully considered but they are not persuasive. Applicant argues that Sheridan does not disclose dual function flippable insert. However, Sheridan discloses a tube that, specifically stated by Sheridan, can be used for administering anesthesia (col. 1, lines 15-22) and a guide for a catheter tube (col. 1, lines 28-32). Therefore, there are at least two functions, for which the Sheridan tube may be used. Moreover, the Sheridan device would be fully capable of being used for any other contemplated usage that involves of tube of its configuration, which could be a feeding tube, post surgical drainage tube, or airway tube.

The Sheridan device is fully capable of being flappable, because it may be removed and reinserted without destroying the device. The tube would still function in an opposite orientation because it is merely a tube with two open ends and constant diameter, which means it will function while inserted in either direction. It may be easier to insert one side easier, however, that does not preclude the other side from being inserted first. Moreover, Applicant argues that if the tube is inserted in the opposite direction it will not work because of the markings on the tube for determining the depth of the tube. However, the marking not corresponding to the depth of the tube would not preclude the usage of the tube in the opposite direction, this has be demonstrated by

the numerous endotracheal tubes, previously known, that do not have depth markings, but that still function. The depth markings are not essential to the functionality of the tube. In addition, the physician could still use the depth markings; except read them in the opposite direction in order to approximate depth.

Applicant argues the specific SHORE hardness of the device is not a mere design choice because it has a particular function and criticality. However, Applicant has failed to highlight any portion of the specification that states the function and criticality of the specific value of the SHORE hardness. Therefore, the specific numerical value if the SHORE hardness is merely a design choice.

Applicant argues the Sheridan/Field device cannot be bent at a forty degree angle because only Applicant's device is intended to be used by flipping Applicant's device around. However, Examiner fails to understand how Applicant's invention has an bearing on whether the Sheridan/Field device can be bent at forty degrees.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-2, 4, 7, 10-12, and 22-24 rejected under 35 U.S.C. 103(a) as being unpatentable over Sheridan (US Patent 3,508,554) in view of Field (US Patent 5,919,183). Sheridan discloses an esophageal device comprising a slender tube/insert (2) that has multiple functions (col. 1, lines 33-42). The tube/insert (2) comprises a tubular member (4) a first section (8), second section (6), and intermediate section (fig. 2) therebetween; integrally connected. The tube/insert is made of plastic and opaque (col. 5, lines 56-61). Also, the tube/insert (2) has indicia markings (10) to mark the depth of the tube in the user. The first and second sections (8, 6) have front and rear sections, as well as tips (fig. 2). The length and diameter of the tube/insert (2) are about 20 to 90 cm and 2 to 5 mm (col. 4, lines 70-73), respectively.

With respect to the second section front portion extending from about 0.5% to about 50% of the total length of said slender tube/insert (2), the applicant has not disclosed that this specificity implies any particular criticality or useful advantage. Further, Sheridan does not disclose a specific length or range of lengths for the distal section with respect to the total length of the tube/insert (2). Therefore, it would have been obvious to one of ordinary skill in the art to make the second section front portion in accordance with the needs of a particular patient as such would have been a matter of engineering design choice.

The tube/insert is flexible (col. 8, lines 60-62). It is obvious to one of ordinary skill in the art the endotracheal tubes are made of stiff, malleable, and ductile material in order to position a tube in the throat without injuring the user and to allow the tube to bend from the mouth to the throat without collapsing the tube so medical devices, air, or food can pass thought the tube. Sheridan fails to disclose the selected hardness of the first and second sections are between about 50 SHORE A to about 90 SHORE D, the tube is made of PVC, tips of softer material than the intermediate section, an end bent between 25 and 45 degrees that reshapes upon withdrawal, and the first and second sections having a SHORE hardness approximately 20 to 30% less than said selected hardness of said intermediate section. However, Field teaches an endotracheal tube (1) comprising an introducer (2) of hardness between 50 SHORE A and 80 SHORE D (col. 1, lines 53-55), that has a proximal end bent at 40 degrees (col. 2, lines 35-40), which is around 35 degrees, and reshapes upon withdrawal (col. 46-49), and tips softer than the intermediate section (col. 3, lines 26-29); a tube (1) made of PVC (col. 2, lines 19-20) that bends to conform to the throat (col. 2, lines 21-25). Therefore it would be obvious to one of ordinary skill in the art the time of the invention to modify the Sheridan device with the limitations, as taught by Field, in order to make the tube easier to insert into the user's throat. Moreover, either side of the Sheridan/Field tube/insert could be bent at a 40 degree angle and inserted into the patient first.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRANDON JACKSON whose telephone number is (571)272-3414. The examiner can normally be reached on Monday - Friday 8-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on (571)272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brandon Jackson/
Examiner, Art Unit 3772

BLJ

/Patricia Bianco/
Supervisory Patent Examiner, Art Unit 3772